

Message

**From:** Martha M. Rumore [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A04866659DA34061A923A48FED0C6D69-MRUMORE]  
**Sent:** 5/13/2021 9:09:34 PM  
**To:** Jesse C. Dresser [jdresser@FrierLevitt.com]  
**Subject:** RE: FDA Request for T-con

Hi:

I understand that when they filed the 3911 form, FDA asked some questions but here is a bunch of queries from FDA- May 4, May 7, May 13.....and not sure they gave the FDA the right answers....not good. Why was their CS inventory quarantined? We need copies of everything that Abbie provided to the FDA. What is T-con???

I can be on the call with them on Monday with FDA.

Best,  
Martha

Martha M. Rumore, PharmD, MS, JD, LLM  
Senior Counsel

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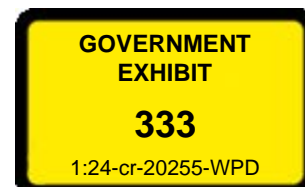
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**From:** Jesse C. Dresser <[jdresser@FrierLevitt.com](mailto:jdresser@FrierLevitt.com)>  
**Sent:** Thursday, May 13, 2021 4:57 PM  
**To:** Martha M. Rumore <[mrumore@frierlevitt.com](mailto:mrumore@frierlevitt.com)>  
**Subject:** FW: FDA Request for T-con

Martha:

I don't know about you but I think this looks not great. Why weren't they making us aware of the fact that they were being asked questions by the FDA?



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FL00021404  
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Jesse C. Dresser, Esq.

**FRIER LEVITT**  
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**From:** Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>  
**Sent:** Thursday, May 13, 2021 2:29 PM  
**To:** Jesse C. Dresser <[jdresser@FrierLevitt.com](mailto:jdresser@FrierLevitt.com)>; Martha M. Rumore <[mrumore@frierlevitt.com](mailto:mrumore@frierlevitt.com)>  
**Subject:** FW: FDA Request for T-con

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]

Hi guys,

Please see below from the FDA. Do you recommend us having council on the call or does that make us look guilty? Please advise.



**Charlie Boyd** | Founder & CEO  
Safe Chain Solutions, LLC  
822 Chesapeake Drive | Cambridge, MD 21613  
office: 855.437.5727 | Cell: 301.875.1581  
[www.SafeChain.com](http://www.SafeChain.com) | [Linked](#) 

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**From:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>  
**Sent:** Thursday, May 13, 2021 11:24 AM  
**To:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>; Shared Mailbox - compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>  
**Subject:** RE: FDA Request for T-con

Hello Christina,  
Yes, we can make that work. Please go ahead and send us the invite.

Thank you,

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**Abbie Divilio** | Director of Compliance  
Safe Chain Solutions, LLC  
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office: 855.437.5727 x1017 | fax: 866.930.1128  
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**From:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>

**Sent:** Thursday, May 13, 2021 10:59 AM

**To:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>; Shared Mailbox - compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>

**Subject:** FDA Request for T-con

Good morning,

FDA would like to have a phone call with representatives from Safe Chain on Monday, May 17<sup>th</sup>, at 3:30. Please let me know if you are available and I will send over a calendar invite.

Thank you,  
Christina

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**From:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>

**Sent:** Friday, May 07, 2021 2:04 PM

**To:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>

**Subject:** [EXTERNAL] RE: FDA 3911 - 45802703

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Hi Christina,

Attached are the documents you've requested and a key to what each one represents:

102 Inventory- controlled substance inventory

101 Inventory- Expired product from the warehouse. These items stay in the quarantine area until our reverse distributor comes to pick them up, which is once a quarter.

061 Inventory- These are the HIV drugs and items we have quarantined

SCS Vendors- list of vendors we use.

Customer Letter- Letter we sent to customers regarding lots of concern.

1. Provide a list (including quantity) of **all** Safe Chain products currently under quarantine, and identify their location. Include Gilead, as well as non-Gilead products.  
Attached
2. What is the date of the last Gilead product that Safe Chain distributed? Who was it supplied by? Provide the name and location of the supplier.  
We have been selling Gilead drugs as recently as this week. We are currently using supply purchased from vendor Synergy Group Wholesale, 491 Amwell Road Suite 103, Hillsborough, NJ
3. Provide a list of all suppliers (including their location) Safe Chain uses for Gilead and non-Gilead products.  
Attached

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4. Provide a list of all dispensers (both name and location) who have quarantined product from Safe Chain in their possession. Provide the specific drug product name and quantity quarantined at each dispenser.  
When we contacted customers regarding lots of concern regarding Gilead products we asked that they coordinate with their sales person to return inventory back to us, so that we could quarantine. We received responses from a few customers who returned inventory, and those pieces are included in the quarantine report.
5. Has Safe Chain communicated with the dispensers who have quarantined product? If so, what was the date and mode of communication (e.g., in writing, telephone call)?  
No, to our knowledge none of our customers still have any product in their inventory.
6. Can Safe Chain assure that quarantined product that is with dispensers will not be dispensed to consumers?  
No, those customers who did not respond to the letters, or request to return the product could still have this in their possession or have already dispensed the drug.

Thanks,



**Abbie Divilio** | Director of Compliance  
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**From:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>

**Sent:** Tuesday, May 4, 2021 3:05 PM

**To:** compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>

**Subject:** RE: FDA 3911 - 45802703

Good afternoon,

Please see questions below. I look forward to your responses.

Thank you,  
Christina

1. Provide a list (including quantity) of **all** Safe Chain products currently under quarantine, and identify their location. Include Gilead, as well as non-Gilead products.
2. What is the date of the last Gilead product that Safe Chain distributed? Who was it supplied by? Provide the name and location of the supplier.
3. Provide a list of all suppliers (including their location) Safe Chain uses for Gilead and non-Gilead products.
4. Provide a list of all dispensers (both name and location) who have quarantined product from Safe Chain in their possession. Provide the specific drug product name and quantity quarantined at each dispenser.
5. Has Safe Chain communicated with the dispensers who have quarantined product? If so, what was the date and mode of communication (e.g., in writing, telephone call)?
6. Can Safe Chain assure that quarantined product that is with dispensers will not be dispensed to consumers?

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GX 333.0004

**From:** compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>  
**Sent:** Tuesday, April 20, 2021 3:35 PM  
**To:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>  
**Subject:** RE: [EXTERNAL] RE: FDA 3911 - 45802703

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OK- thank you for the information.



**Abbie Divilio** | Director of Compliance  
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**From:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>  
**Sent:** Tuesday, April 20, 2021 3:30 PM  
**To:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>  
**Subject:** RE: [EXTERNAL] RE: FDA 3911 - 45802703

Hi Abbie,

Because these products have been identified as illegitimate, you are required to quarantine the product until further instruction is provided. Do not return or process these products as returns at this time.

Thank you,  
Christina

**From:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>  
**Sent:** Tuesday, April 20, 2021 3:23 PM  
**To:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>  
**Subject:** [EXTERNAL] RE: FDA 3911 - 45802703

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Hi Christina,

We have product sitting in our quarantine from two vendors, one is Rapids Tex and the other is Boulevard 9229. These are all HIV medications from Gilead. We would like to return them to the vendor as we have not paid for them while we investigated and reported these items to the FDA. We are now at the point where these two vendors are demanding payment or to return the product. We would like to return it ASAP, do you see a problem with us doing that?



Your input is appreciated,



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**From:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>

**Sent:** Thursday, April 15, 2021 8:06 PM

**To:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>

**Subject:** RE: FDA 3911 - 45802703

Thank you. Can you please provide the following information:

1. What is Safe Chain doing with the products that are named in the falsified pedigrees? (Biktarvy and all other products)
2. Is Safe Chain still purchasing products from unauthorized distributors? If so, which distributors?
3. What is Safe Chain's strategy moving forward to ensure you are not purchasing/distributing products that are unsafe for consumers?

Many thanks,  
Christina

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**From:** Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>

**Sent:** Monday, April 12, 2021 8:51 AM

**To:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>; Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>

**Subject:** [EXTERNAL] RE: FDA 3911 - 45802703

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Christina,

One bottle was shipped to a customer who we have contacted. We have not heard if that bottle has been dispensed to a patient or is still in the pharmacies inventory. This bottle was released before we heard back from Gilead that these transactions were inconsistent with their records.



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FL00021409  
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**From:** Picard, Christina M <[Christina.Picard@fda.hhs.gov](mailto:Christina.Picard@fda.hhs.gov)>  
**Sent:** Friday, April 9, 2021 12:04 PM  
**To:** Charles Boyd <[CharlesB@Safechain.com](mailto:CharlesB@Safechain.com)>; compliance <[compliance@Safechain.com](mailto:compliance@Safechain.com)>; Abbie Divilio <[AbbieD@Safechain.com](mailto:AbbieD@Safechain.com)>  
**Subject:** FDA 3911 - 45802703

Good morning,

Can you please advise, today if possible, if any of the 177 bottles referenced in attached 3911 were distributed? Or were all quarantined?

Thank you,  
Christina

*Christina M. Picard, J.D.  
Regulatory Counsel  
CDER, Office of Compliance  
Office of Drug Security, Integrity, and Response  
Division of Supply Chain Integrity  
301-796-4953*

FL00021410  
FL00021404

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